



European Monitoring Centre
for Drugs and Drug Addiction

GUIDANCE NOTE 6

Intensive monitoring

EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances

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1. Purpose

The purpose of this document is to provide general guidance on the intensive monitoring of new psychoactive substances by the EMCDDA.

What is intensive monitoring?

All new psychoactive substances are monitored by the EMCDDA at the point of formal notification. During the course of monitoring, the EMCDDA may identify signals that suggest that a new psychoactive substance *might* pose severe public health or social risks. These substances are subject to intensive monitoring so that the EMCDDA can better monitor, assess, and understand the risks that the substance may pose. They are placed on the intensive monitoring list and regularly reviewed.

As part of intensive monitoring, the EMCDDA may request additional information from the Network and/or conduct regular searches for information in the scientific literature and other open sources in order to better understand the risks that the substance might pose.

Requests for additional data may be made to the entire Network through a risk communication or requested from one or more members of the Network through a request for information. The information is used as part of the signal management system to inform which responses the EMCDDA may undertake in order to reduce the public health or social risk.

Which substances are intensively monitored?

Intensive monitoring is usually applied to a new psychoactive substance based on:

- reports of health problems
- reports of social problems
- reports of seized material
- pharmacological and toxicological properties of the new psychoactive substance or analogy with better-studied substances
- potential for further spread.

The data are assessed by the EMCDDA during a signal review meeting at which time a recommendation may be made to add the substance to the intensive monitoring list.

The EMCDDA will inform the Network in a timely manner by email when a new psychoactive substance is added or removed from the intensive monitoring list along with the reason for this.

Any event linked to a substance under intensive monitoring is classed as an event of potential high impact on public health (Guidance Note 4). As such, Member States should expedite reporting of these types of events in order to support the early detection, assessment, and timely response to public health and social risks both at national and EU level.

When is a substance removed from the intensive monitoring list?

A new psychoactive substance is removed from the intensive monitoring list if the EMCDDA determines that it does not appear to pose severe public health or social risks. A substance may be added again to the list should additional data become available that suggests that it might pose severe public health or social risks.

In addition, a new psychoactive substance will also be removed from the list of intensive monitoring should it be controlled under EU legislation in accordance with Council Framework Decision 2004/757/JHA (as amended) or by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances.

The intensive monitoring list is available on the European Database on New Drugs (EDND) at:

Home > Additional Resources > Intensive Monitoring List

The guidance provided in this document will not fit every possible situation perfectly, and may need to be adapted in order to effectively respond to a specific event or situation. In such cases, the Reitox national focal points should contact the EMCDDA for advice as soon as possible.

→ You can contact us at: ews@emcdda.europa.eu

2. Scope

This Guidance Note applies to the EMCDDA and Reitox national focal points.

3. Changes since last revision

Not applicable. Initial Guidance Note.

4. Responsibilities

It is the responsibility of the EMCDDA to ensure that this Guidance Note is adhered to.

5. Documents needed for this Guidance Note:

- EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances.
- Guidance Note 2: Types of Information that should be reported by the Member States on a new psychoactive substance
- Guidance Note 3: Events of potential high impact on public health
- Guidance Note 5: Intensive monitoring

6. Related documents

- Regulation (EC) No 1920/2006 (as amended).
<http://data.europa.eu/eli/reg/2006/1920/2018-11-23>
- Council Framework Decision 2004/757/JHA (as amended).
http://data.europa.eu/eli/dec_framw/2004/757/2017-11-22

7. Terminology and definitions

- Guidance Note 1: Terminology and definitions

8. Additional information

None.

9. Changes since last version

Not applicable.